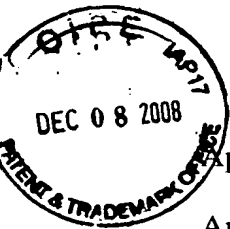


12-09-08

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Express Mail No.: EM 198 023 831 US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Palese *et al.*

Confirmation No.: 4596

Application No.: 10/724,273

Group Art Unit: 1648

Filed: November 24, 2003

Examiner: Parkin, Jeffrey S.

For: NUCLEIC ACIDS ENCODING A NOVEL
INFLUENZA VIRUS NON-STRUCTURAL
PROTEIN (NS1)-BINDING PROTEIN HOST
FACTOR DESIGNATED NS1I-1

Attorney Docket No.: 6923-119

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

MAIL STOP ISSUE FEE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance, mailed September 9, 2008, from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/724,273 (hereinafter "the '273 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. 154(b) stating that the projected patent term adjustment to date is 567 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) ("Determination") mailed September 9, 2008. Specifically, Applicants believe that the patent term adjustment of 567 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, should be, at a minimum, equal to the period starting November 24, 2003 and ending January 24, 2005 (618 days) plus the period starting November 25, 2006 and ending the day that a patent issues on the above-identified application (estimated to be 865 days), minus 163 days for the period beginning on the date on which a notice of appeal was filed and ending on the date of mailing of a notice of allowance, as required under 37 C.F.R. § 1.703(b)(4). For the purpose of this Request, Applicants assume that the patent will issue on the above-identified application on April 7,

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2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request. Applicants believe that the patent term adjustment should be, at a minimum, a total of 1,229 days.

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following statement of facts:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be \$200.00.

Please charge the required fee to Jones Day Deposit Account No. 50-3013 (referencing 702827-999118).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 1,229 days, assuming that the patent on the above-identified application issues on April 7, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request, which number of days is attributable to the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '273 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)) (the "A period") minus the number of actual calendar days occurring in both the A period and in the "B period" described below; and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '273 application (delay under 37 C.F.R. § 1.702(b)) minus the number of days in the period beginning on the date in which a Notice of Appeal was filed and ending on the date of mailing of a notice of allowance (see 37 C.F.R. § 1.703(b)(4)) (the "B period") and minus the time during this period consumed by Applicant delay (see 35 U.S.C. § 154(b)(1)(B)(iii) and 37 C.F.R. § 1.703(b)).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a) (the "A period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is 618 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '273 application. See PTO's Patent Application Information Retrieval page for U.S. Application No. 10/724,273 at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A). The '273 application was filed under 35 U.S.C. § 111(a) on November 24, 2003. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on October 4, 2006. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on which the application was filed (*i.e.*, by January 24, 2005), and thus, the delay under 37 C.F.R. § 1.702(a)(1) includes 618 days.

In sum, the number of days of delay in the A period, that is, under subsection (a)(1) of 37 C.F.R. § 1.702 is 618 days.

(b) Delay under 37 C.F.R. § 1.702(b) (the "B period")

The delay by the PTO under 37 C.F.R. § 1.702(b) is 702 days, assuming that the patent on the above-identified application issues on Tuesday, April 7, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

The '273 application was filed under 35 U.S.C. § 111(a) on November 24, 2003. A patent has not yet issued, however, an Issue Fee payment authorization accompanies this Request. Accordingly, the PTO has not issued a patent within three years of the date on which the application was filed (in this case, November 24, 2006), and thus, the term of the patent should be adjusted because issuance has been delayed by 865 days, minus the period beginning on the date in which a Notice of Appeal was filed (March 31, 2008) and ending on the date of mailing of a notice of allowance (September 9, 2008) (163 days) (see 37 C.F.R. § 1.703(b)(4)). Assuming that the patent on the above-identified application issues on Tuesday, April 7, 2009, Applicants submit that the period of delay by the PTO in the B period will be 865 days minus 163 days, or 702 days. See 37 C.F.R. § 1.702(b). This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (see "PTO PAIR Adjustment," Exhibit A). However, as required under 35 U.S.C. § 154(b)(1)(B)(iii), the extension of the term of the patent by 1 day for each day after the end of that 3-year period is reduced by any delay in the processing of the application by the PTO that was requested by Applicants (see also 37 C.F.R. § 1.704(b)). As recognized in the PTO calculation of the patent term adjustment, this reduction is 91 days. Therefore, the total patent term adjustment for delay in issuance of the patent under the B period is 702 days minus 91 days, or 611 days.

(c) Overlapping Days in the Delay Periods

According to 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." See 35 U.S.C. § 154(b)(2)(A).

Applicants submit that there was no overlap of the actual calendar days of the A period, discussed in detail below, with the actual calendar days of the B period. Thus, the period of patent term adjustment on a patent that issues on the above-identified patent application is calculated as the sum of 618 plus 611, which is equal to 1,229 days.

Applicants respectfully submit that under controlling case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R.

§ 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Dudas*, No. 07-1492, Doc No. 27 (D.D.C. September 30, 2008) (hereinafter *Wyeth*), a copy of which is included here as Exhibit B.

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

Turning to the '273 application, the period of delay under subsection (a)(1) of 37 C.F.R. § 1.702 includes the days of November 24, 2003, to October 4, 2006 (618 days). The delay under 37 C.F.R. § 1.702(b) comprises November 25, 2006 to the day the patent on the '273 application issues. Thus, the delay under 37 C.F.R. § 1.702(a)(1) occurring from November 24, 2003, to October 4, 2006 (618 days) occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (November 25, 2006 to the day the patent on the '273 application issues). Consequently, under 35 U.S.C. § 154(b)(2)(A), there are 618 days under 37 C.F.R. § 1.702(a) that do not overlap the 611 days of delay under 37 C.F.R. § 1.702(b) for the '273 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a) and 37 C.F.R. § 1.702(b), or **1,229** days (the sum of 618 and 611 days), assuming that the patent on the '273 application issues on Tuesday, April 7, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

- 1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.” In particular, Applicants seek to include the delay under 37 C.F.R. § 1.702(a)(1) occurring from November 24, 2003 to October 4, 2006 (618 days) that occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b).

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.”

Applicants submit that this period consists of 611 days for the period beginning the day after November 24, 2006 (the date that is three years after the date on which the '273 application was filed) and ending on the day that a patent issues on the '273 application, assuming that the patent on the '273 application issues on Tuesday, April 7, 2009, which is the Tuesday before the date that is four months after the mailing date of the issue fee payment, which accompanies this Request.

Applicants further submit that the 618 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 611 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants' believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 1,229 days, not 567 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a) and (b) amounts to 1,229 days. As discussed *supra* in section 2(i)(2)(b) and in section (iv) below, Applicants believe that there was a period of 91 days constituting a delay attributable to Applicants under 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.704. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 1,229 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 618 days plus 702 days), less the sum of the period calculated under Section 1.704(b) (*i.e.*, 91 days).

- (iii) The '273 application is not subject to a terminal disclaimer.
- (iv) In accordance with the 91 days for Applicant delay indicated by PTO in its calculation of the patent term adjustment (*see* PTO PAIR Adjustment, Exhibit A), Applicants believe that there were no other circumstances constituting a failure by Applicants to engage in reasonable efforts to conclude processing or examination of the '273 application.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 1,320 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 91 days, and thus the total

period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 1,229 days.

Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 1,229 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that “[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*” (emphasis added). An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Respectfully submitted,

Date: December 8, 2008

Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)

By:

Jennifer J. Chheda 46,617
Jennifer J. Chheda (Reg. No.)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

EXHIBIT A: PTO PAIR Adjustment

10/724,273	NUCLEIC ACIDS ENCODING A NOVEL INFLUENZA VIRUS NON-STRUCTURAL PROTEIN (NS1)-BINDING HOST FACTOR DESIGNATED NS1I-1.	12-07-2008::09:55:37
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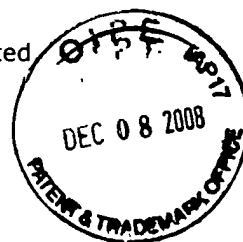
Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/724,273

Filing or 371(c) Date:	11-24-2003	USPTO Delay (PTO) Delay (days):	658
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	91
Post-Issue Petitions (days):	+0	Total PTA (days):	567
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-09-2008	Mail Notice of Allowance	40	
09-09-2008	Document Verification	↑	
09-09-2008	Examiner's Amendment Communication	↑	
09-09-2008	Notice of Allowance Data Verification Completed	↑	
09-09-2008	Case Docketed to Examiner in GAU	↑	
07-21-2008	Request for Extension of Time - Granted	↑	
08-27-2008	Date Forwarded to Examiner	↑	
07-21-2008	Supplemental Response	↑	
05-16-2008	Mail Advisory Action (PTOL - 303)	↑	
05-12-2008	Advisory Action (PTOL-303)	↑	
04-10-2008	Date Forwarded to Examiner	↑	
03-31-2008	Amendment/Argument after Notice of Appeal	↑	
03-31-2008	Notice of Appeal Filed	↑	
12-31-2007	Mail Final Rejection (PTOL - 326)		
12-26-2007	Final Rejection		
10-01-2007	Information Disclosure Statement considered		
10-31-2007	CRF Is Good Technically / Entered into Database		
10-01-2007	Reference capture on IDS		
10-01-2007	Information Disclosure Statement (IDS) Filed		
10-01-2007	Substitute Specification Filed		
10-01-2007	Miscellaneous Incoming Letter		
10-15-2007	Date Forwarded to Examiner		
10-01-2007	Response after Non-Final Action		31
10-01-2007	Request for Extension of Time - Granted		↑
10-01-2007	Information Disclosure Statement (IDS) Filed		↑
05-31-2007	Mail Non-Final Rejection		↑
05-29-2007	Non-Final Rejection		
03-20-2007	Date Forwarded to Examiner		
03-05-2007	Response to Election / Restriction Filed		60
03-05-2007	Request for Extension of Time - Granted		↑



10-04-2006	Mail Restriction Requirement	618
10-02-2006	Requirement for Restriction / Election	↑
09-22-2005	IFW TSS Processing by Tech Center Complete	↑
09-22-2005	Case Docketed to Examiner in GAU	↑
11-24-2003	Preliminary Amendment	↑
05-23-2005	Application Dispatched from OIPE	↑
05-24-2005	Application Is Now Complete	↑
05-04-2005	Payment of additional filing fee/Preexam	↑
11-24-2003	Claim Preliminary Amendment	↑
05-04-2005	Applicant has submitted new drawings to correct Corrected Papers problems	↑
02-04-2005	Notice Mailed--Application Incomplete--Filing Date Assigned	↑
08-27-2004	CRF Is Good Technically / Entered into Database	↑
11-24-2003	CRF Disk Has Been Received by Preexam / Group / PCT	↑
01-12-2004	Cleared by OIPE CSR	↑
12-25-2003	IFW Scan & PACR Auto Security Review	↑
11-24-2003	Initial Exam Team nn	↑

[Close Window](#)

EXHIBIT B: Copy of *Wyeth et al. v. Dudas*

WYETH, et al.,

V.

Civil Action No. 07-1492 (JR)

Defendant.

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap, Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds

specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C.

§ 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. See 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO.¹ See 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

¹ Certain reasons for exceeding the three-year pendency period are excluded, see 35 U.S.C. § 154(b)(1)(b)(i)-(iii), as are periods attributable to the applicant's own delay. See 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, see 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is

1/1/07, but the patent does not issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under Chevron v. NRDC, 467 U.S. 837 (1984). No, the plaintiffs argue, because, under the Supreme Court's holdings in Gonzales v. Oregon, 546 U.S. 243 (2006), and United States v. Mead Corp., 533 U.S. 218 (2001), Congress has not "delegated authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority.

See Gonzales, 546 U.S. at 255-56, citing Mead, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded Chevron deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See Merck & Co. v. Kessler, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in Merck, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). Chevron deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at Chevron's "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., MCI v. AT&T, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" always overlaps with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application delayed under § 154(b)(1)(B) during the

period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that - again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefitted by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and no more, it could easily have been written that way. It is true that the legislative context -- as

distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C.

§ 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA



WYETH, et al.,

Plaintiffs,

v.

JON W. DUDAS, Under Secretary of
Commerce for Intellectual
Property and Director of U.S.
Patent and Trademark Office,

Defendant.

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: Civil Action No. 07-1492 (JR)
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ORDER

For the reasons stated in the accompanying memorandum opinion, plaintiffs' motion for summary judgment [12] is **GRANTED** and defendant's motion for summary judgment [16] is **DENIED**. The case is remanded to the agency for further proceedings that are consistent with this opinion.

JAMES ROBERTSON
United States District Judge